RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-8-27
STANDARDS FOR HOME CARE ORGANIZATIONS
PROVIDING HOSPICE SERVICES

TABLE OF CONTENTS

1200-8-27-.01 DEFINITIONS.

(1) Administrator. A person who:

(a) Is a licensed physician with at least one (1) year supervisory or administrative experience in home health care, hospice care or related health programs; or

(b) Is a registered nurse with at least one (1) year supervisory or administrative experience in home health care, hospice care or related health programs; or

(c) Has training and experience in health service administration and at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs.

(2) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.

(3) Agency. A Home Care Organization providing hospice services.

(4) Bereavement Counselor. An individual who has at least a bachelor's degree in social work, counseling, psychology, pastoral care or specialized training or experience in bereavement theory and counseling.

(5) Board. The Tennessee Board for Licensing Health Care Facilities.

(6) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(7) Certified Master Social Worker. A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.

(Rule 1200-8-27-.01, continued)

(8) Clinical Note. A written and dated notation containing a patient assessment, responses to medications, treatments, services, any changes in condition and signed by a health team member who made contact with the patient.

(9) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(10) Competent. A patient who has decision-making capability.

(11) Core Services. Services consisting of nursing, medical social services, physician services and counseling services.

(12) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual event,

(b) the time frames for the action(s) to be implemented,

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(13) Decision-making capacity. Decision-making capacity is shown by the fact that the person is able to understand the proposed procedure, its risks and benefits, and the available alternative procedures.

(14) Department. The Tennessee Department of Health.

(15) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(16) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(17) Health care decision. A decision made by an individual or the individual's health care decision-maker, regarding the individual's health care including but not limited to:

(a) the selection and discharge of health-care providers and institutions;

(b) approval or disapproval of diagnostic tests, surgical procedures, programs of administration of medication, and orders not to resuscitate;

(c) directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care; and

(d) transfer to other health care facilities.

(18) Health Care Decision-maker. In the case of an incompetent patient, or a patient who lacks decision-making capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed legal guardian or

conservator with health care decision-making authority, or the patient's surrogate as determined pursuant to Rule 1200-8-27-.13 or T.C.A. §33-3-220.

(19) Home Care Organization. As defined by T.C.A. § 68-11-201, a "home care organization" provides home health services, home medical equipment services or hospice services to patients on an outpatient basis in either their regular or temporary place of residence.

(20) Home Health Aide/Hospice Aide. A person who has completed a total of seventy-five (75) hours of training which included sixteen (16) hours of clinical training prior to or during the first three (3) months of employment and who is qualified to provide basic services, including simple procedures as an extension of therapy services, personal care regarding nutritional needs, ambulation and exercise, and household services essential to health care at home.

(21) Homemaker Service. A non-skilled service in the home to maintain independent living which does not require a physician's order. An agency does not have to be licensed as a home care organization to provide such services.

(22) Hospice Services. As defined by T.C.A. § 68-11-201, "hospice services" means a coordinated program of care, under the direction of an identifiable hospice administrator, providing palliative and supportive medical and other services to hospice patients and their families in the patient's regular or temporary place of residence. Hospice services shall be provided twenty-four (24) hours a day, seven (7) days a week.

(23) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(24) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(25) Lacks Decision-Making Capacity. Lacks Decision-Making Capacity means the factual demonstration by the attending physician and the medical director, or the attending physician and another physician that an individual is unable to understand:

(a) A proposed health care procedure(s), treatment(s), intervention(s), or interaction(s);

(b) The risks and benefits of such procedure(s), treatment(s), intervention(s) or interaction(s); and

(c) The risks and benefits of any available alternative(s) to the proposed procedure(s), treatment(s), intervention(s) or interaction(s).

(26) Legal Guardian. Any person authorized to act for the resident pursuant to any provision of T.C.A. §§34-5-102(4) or 34-11-101, or any successor statute thereto.

(27) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(28) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(29) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(30) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(Rule 1200-8-27-.01, continued)

(31) Medical Record. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries and other written electronic or graphic data prepared, kept, made or maintained in an agency that pertains to confinement or services rendered to patients.

(32) Medical Social Services. Medical social services must be provided by a qualified social worker under the direction of a physician, in accordance with the plan of care.

(33) Medically Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the surrogate expresses the goals of the patient.

(34) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(35) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(36) Palliative. The reduction or abatement of pain or troubling symptoms, by appropriate coordination of all elements of the hospice care team, to achieve needed relief of distress.

(37) Patient. Hospice patient means only a person who has been diagnosed as terminally ill; been certified by a physician in writing to have an anticipated life expectancy of six (6) months or less; has voluntarily through self or a surrogate requested admission to a hospice; and been accepted by a licensed hospice.

(38) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed “patient abuse” for purposes of these rules.

(39) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(40) Physical Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(41) Physician. A person currently licensed as such by the Tennessee Board of Medical Examinations or currently licensed by the Tennessee Board of Osteopathic Examination. For the purpose of this chapter only, a physician who is licensed to practice medicine or osteopathy in a state contiguous to Tennessee, who has previously provided treatment to the patient and has an ongoing physician-patient relationship with the person for whom a referral is to be made, may refer a patient residing in this state to a home care organization providing hospice services duly licensed under this chapter. This shall not be construed as authorizing an unlicensed physician to practice medicine in violation of T.C.A. §§ 63-6-204 or 63-9-104.

(42) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(43) Respiratory Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(Rule 1200-8-27-.01, continued)

(44) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(45) Respite Care. A short-term period of inpatient care provided to the patient only when necessary to relieve the family members or other persons caring for the patient.

(46) Shall or Must. Compliance is mandatory.

(47) Social Work Assistant. A person who has a baccalaureate degree in social work, psychology, sociology or other field related to social work, and has at least one (1) year of social work experience in a health care setting. Social work related fields include bachelor/masters degrees in psychology, sociology, human services (behavioral sciences, not human resources), masters degree in counseling fields (psychological guidance and guidance counseling) and degrees in gerontology.

(48) Speech Language Pathologist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.

(49) Spiritual Counselor. A person who has met the requirements of a religious organization to serve the constituency of that religious organization.

(50) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(51) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.

(52) Surrogate. The patient's legal guardian, or, if none, a competent adult most likely to know the wishes of the patient with respect to the possible withholding of resuscitative services or withdrawal of resuscitative services.

(53) Terminally ill. An individual with a medical prognosis that his or her life expectancy is six (6) months or less if the illness runs its normal course.

(54) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.

(55) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

(56) Volunteer. An individual who agrees to provide services to a hospice care patient and/or family member(s), without monetary compensation, in either direct patient care or an administrative role and supervised by an appropriate hospice care employee.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003.*

1200-8-27-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate or maintain in the State

of Tennessee any Home Care Organization providing Hospice Services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic area specified by the certificate of need or at the time of the original licensing. The name of the agency shall not be changed without first notifying the Department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the agency.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the Department.

(b) Each applicant for a license shall pay an annual license fee of $800.00. The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Patients shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.

(d) The applicant must prove the ability to meet the financial needs of the agency.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.

(a) For the purposes of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the agency is owned and operated.

(c) Transactions constituting a change of ownership include, but are not limited to the following:

1. Transfer of the agency's legal title;

2. Lease of the agency's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the agency;

4. One partnership is replaced by another through the removal, addition or substitution of a partner;

5. Removal of the general partner or general partners, if the agency is owned by a limited partnership;

(Rule 1200-8-27-.02, continued)

6. Merger of an agency owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate agency owner with one or more corporations; or

8. Transfers between levels of government.

(d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or

5. Corporate stock transfers or sales, even when a controlling interest.

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the agency. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the agency's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) To be eligible for a license or renewal of a license, each agency shall be periodically inspected for compliance with these regulations. If deficiencies are identified, an acceptable plan of correction shall be established and submitted to the Department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed November 19, 2003; effective February 2, 2004.*

1200-8-27-.03 DISCIPLINARY PROCEDURES.

(1) The Board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the agency;

(d) Conduct or practice found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency; or

(e) Failure to renew the license.

(2) The Board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(Rule 1200-8-27-.03, continued)

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patient in the agency;

(c) The conduct of the agency in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and

(d) Any prior violations by the agency of statutes, rules or orders of the Board.

(3) When an agency is found by the Department to have committed a violation of this chapter, the Department will issue to the agency a statement of deficiencies. Within ten (10) days of receipt of the statement of deficiencies the agency must return a plan of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(4) Either failure to submit a plan of correction in a timely manner or a finding by the Department that the plan of correction is unacceptable shall subject the agency's license to possible disciplinary action.

(5) Any licensee or applicant for a license, aggrieved by a decision or action of the Department or Board, pursuant to this chapter, may request a hearing before the Board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Administrative Procedures Act, T.C.A. §§ 4-5-101, et seq.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, and 68-11-206 through 68-11-209.* ***Administrative History:*** *Original rule filed April 25, 1996; effective July 9, 1996. Repeal and new rule filed April 17, 2000; effective July 1, 2000.*

1200-8-27-.04 ADMINISTRATION.

(1) Governing Body. A hospice service program must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospice program's total operation. The governing body must designate an individual who is responsible for the day to day management of the hospice program. The governing body must also ensure that all hospice services provided are consistent with accepted standards of practice.

(2) The hospice agency must organize, manage and administer its hospice services to attain and maintain the highest practicable functional capacity for each patient in a manner consistent with acceptable standards of practice.

(3) The hospice agency shall ensure a framework for addressing issues related to care at the end of life.

(4) The hospice agency shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

(Rule 1200-8-27-.04, continued)

(5) Nursing services, physician services, drugs and biologicals shall routinely be available on a 24-hour basis.

(6) All other hospice services shall be available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness or conditions directly attributable to the terminal diagnosis.

(7) Professional Management. A hospice service program may contract for another individual or entity to furnish services, other than core services, to the hospice program's patients. If services are provided under agreement or contract, the hospice program must meet the following standards:

(a) Continuity of care. The hospice program assures the continuity of patient/family care.

(b) Written agreement. The hospice service program has a legally binding written agreement for the provision of hospice services. The agreement includes at least the following:

1. Identification of the services to be provided.

2. A stipulation that services may be provided only with the express authorization of the hospice program.

3. The manner in which the contracted services are coordinated, supervised and evaluated by the hospice program.

4. The delineation of the role(s) of the hospice program and the contractor in the admission process, patient/family assessment and the interdisciplinary group care conferences.

5. Requirements for documenting that services are furnished in accordance with the agreement.

6. The qualifications of the personnel providing the services.

(c) Professional management responsibility. The hospice program retains professional management responsibility for those contracted services and ensures that they are furnished in a safe and effective manner by persons meeting the qualifications of this chapter, and in accordance with the patient's plan of care and the other requirements of this chapter.

(d) Financial responsibility. The hospice program retains responsibility for payment for services.

(8) The organizational structure, hospice services provided, administrative control and lines of authority for the delegation of responsibility down to the patient care level shall be clearly set forth in writing and shall be readily identifiable. Administrative and supervisory functions shall not be delegated to another agency. All hospice services not provided directly by the licensed agency shall be monitored and controlled by that agency. Supervisory functions shall not be delegated to another home care organization. When a home care organization provides hospice services at more than one location, it must comply with the following:

(a) Each location must provide the same full range of services that is required of the hospice issued license (parent);

(b) Each location must be responsible to the same governing body and central administration that governs the hospice issued license (parent), and the governing body and central administration must be able to adequately manage each location;

(c) Clinical records must be maintained for all patients, regardless of where services are provided; and

(d) All hospice patients' clinical records requested by the surveyor must be available at the hospice site issued the license (parent).

If a home care organization providing hospice services at an additional location is unable to comply with these requirements, it is operating as a separate entity, and must be separately licensed.

(9) The administrator shall organize and direct the organization's ongoing functions; maintain ongoing liaison among the governing body, the professional personnel and the staff; employ qualified personnel and ensure adequate staff education and evaluation for all personnel involved in direct patient care; ensure the accuracy of public information materials and activities; and implement an effective budgeting and accounting system. A person with sufficient experience and training shall be authorized in writing to assume temporary duty during the administrator's short-term absence.

(10) An agency shall have a duly qualified administrator accessible during normal operating hours. Any change of administrators shall be reported to the Department within fifteen (15) days.

(11) An administrator shall serve no more than one (1) licensed home care organization unless that home care organization provides other categories of home care organization services under the same ownership and at the same location.

(12) The agency shall maintain an office with a working telephone and be staffed during normal business hours.

(13) When licensure is applicable for a particular job, a copy of the current license or the number and renewal number of the current license must be maintained in the personnel file. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Proof of adequate medical screenings to exclude communicable disease shall be maintained in the file of each employee.

(14) Personnel practices shall be supported by written personnel policies. Personnel records shall include at a minimum: job descriptions, verification of references and credentials, and performance evaluations. Personnel records must be kept current.

(15) An ongoing educational program shall be planned and conducted for the development and improvement of skills of all the organization's personnel engaged in delivery of hospice services. Each employee shall receive appropriate orientation to the organization, its policies, the employee's position, and the employee's duties. Records shall be maintained which indicate the subject of and attendance at such staff development programs.

(16) If personnel under hourly or per visit contracts are utilized by the agency, there shall be a written contract between such personnel and the organization clearly designating:

(a) That patients are accepted for care only by the agency;

(b) Which hospice services are to be provided;

(c) That it is necessary to conform to all applicable organization policies including personnel qualifications;

(d) The responsibility for participating in developing plans of care;

(e) The manner in which hospice services will be controlled, coordinated and evaluated by the agency;

(f) The procedures for submitting clinical and progress notes, scheduling visits and periodic patient evaluations; and

(g) The procedures for determining charges and reimbursement.

(17) Whenever the rules of this chapter require that a licensee develop a written policy, plan, procedure, technique or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. An agency which violates a required policy also violates the rule establishing the requirement.

(18) Policies and procedures shall be consistent with professionally recognized standards of practice.

(19) All agencies shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.

(20) Each agency utilizing students shall establish policies and procedures for their supervision.

(21) No agency shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the Board, the Department, the Department of Human Services Adult Protective Services or the Comptroller of the State Treasury. An agency shall neither retaliate nor discriminate because of information lawfully provided to these authorities, because of a person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-222.* ***Administrative History:*** *Original filed April 25, 1996; effective July 9, 1996. Repeal and new rule filed April 17, 2000; effective July 1, 2000. Amendment filed June 18, 2002; effective September 1, 2002.*

1200-8-27-.05 ADMISSIONS, DISCHARGES AND TRANSFERS.

(1) The hospice service program shall have a policy to admit only patients who meet the following criteria:

(a) Has been diagnosed as terminally ill;

(b) Has been certified by a physician, in writing, to have an anticipated life expectancy of six (6) months or less;

(c) Has personally or through a representative voluntarily requested admission to, and been accepted by, a licensed hospice service organization; and

(d) Has personally or through a representative, in writing, given informed consent to receive hospice care.

(2) Patients shall be accepted to receive hospice services on the basis of a reasonable expectation that the patient's medical, nursing and psychosocial needs can be met adequately by the organization in the patient's regular or temporary place of residence.

(Rule 1200-8-27-.05, continued)

(3) Care shall follow a written plan of care established and reviewed by the attending physician, the medical director or physician designee and the interdisciplinary group prior to providing care. Care shall continue under the supervision of the attending physician.

(4) The agency staff shall determine if the patient's needs can be met by the organization's services and capabilities.

(5) Every person admitted for care or treatment to any agency covered by these rules shall be under the supervision of a physician as defined in this chapter who holds a license in good standing. The name of the patient's attending physician shall be recorded in the patient's medical record.

(6) The agency staff shall obtain the patient's written consent for hospice services.

(7) The signed consent form shall be included with the patient's individual clinical record.

(8) A diagnosis must be entered in the admission records of the agency for every person admitted for care or treatment.

(9) No medication or treatment shall be provided to any patient of an agency except on the order of a physician or dentist lawfully authorized to give such an order.

(10) A medical record shall be developed and maintained for each patient admitted.

(11) No patient shall be involuntarily discharged without a written order from the attending physician or the medical director stating the patient does not meet hospice criteria, or through other legal processes, and timely notification of next of kin and/or the authorized representative.

(12) When a patient is discharged, a summary of the significant findings and events of the patient's care, the patient's condition on discharge and the recommendation and arrangement for future care, if any, is required.

(13) The agency shall ensure that no person on the grounds of race, color, national origin or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the agency. The agency shall protect the civil rights of patients under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000.*

1200-8-27-.06 BASIC AGENCY FUNCTIONS.

(1) An organization providing hospice services must ensure that substantially all core services are routinely provided directly by hospice employees. A hospice service program may use contracted staff if necessary to supplement hospice service program employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the organization providing hospice services must maintain professional, financial and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this rule.

(a) Nursing services. The hospice service program must provide nursing care and services by or under the supervision of a registered nurse (R.N.) at all times.

1. Nursing services must be directed and staffed to assure the nursing needs of patients are met.

2. Patient care responsibilities of nursing personnel must be specified.

3. Hospice services must be provided in accordance with recognized standards of practice.

4. A registered nurse may make the actual determination and pronouncement of death under the following circumstances:

(i) The deceased was receiving the services of a licensed home care organization providing Medicare-certified hospice services;

(ii) Death was anticipated, and the attending physician and/or the hospice medical director has agreed in writing to sign the death certificate. Such agreement must be present with the deceased at the place of death;

(iii) The nurse is licensed by the state; and,

(iv) The nurse is employed by the home care organization providing hospice services to the deceased.

(b) Medical Social Services. Medical Social Services must be provided by a qualified social worker under the direction of a physician.

(c) Physician Services. In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice service program, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent these needs are not met by the attending physician.

(d) Counseling Services. Counseling services must be made available to both the patient and the family. Counseling includes bereavement counseling, provided both prior to and after the patient's death, as well as dietary, therapeutic, spiritual and any other counseling services identified in the Plan of Care for the patient and family.

1. Bereavement counseling. There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, services to be provided and the frequency of services.

2. Dietary counseling. Dietary counseling, when required, must be provided by a qualified individual.

3. Spiritual counseling. Spiritual counseling must include notice as to the availability of clergy.

4. Additional counseling. Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice program.

(2) Plan of Care. A written plan of care must be established and maintained for each patient admitted to a hospice program and the care provided must be in accordance with the plan.

(a) Establishment of plan. The plan must be established by the attending physician, the medical director or the physician's designee and the interdisciplinary group prior to providing care.

(b) Review of plan. The plan must be reviewed and updated as the patient's condition changes, but at intervals of no more than fourteen (14) days, by the attending physician, the medical director or the physician's designee and the interdisciplinary group. These reviews must be documented.

(c) Content of plan. The plan must include an assessment of the individual's needs and identification of the hospice services required, including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

(3) Interdisciplinary Group. The organization providing hospice services must designate an interdisciplinary group(s) composed of individuals who provide or supervise the care and services offered by the hospice program:

(a) Composition of Group. The hospice service program must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice service program:

1. A doctor of medicine or osteopathy;

2. A registered nurse;

3. A social worker; and

4. A pastoral or other counselor.

(b) Role of Group. The interdisciplinary group is responsible for:

1. Participation in the establishment of the plan of care;

2. Provision or supervision of hospice care and services;

3. Periodic review and updating of the plan of care for each individual receiving hospice care; and

4. Establishment of policies governing the day-to-day provision of hospice care and services.

(c) If a hospice service program has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in part (b) of this paragraph.

(4) Coordinator. The hospice service program must designate a registered nurse to coordinate the implementation of the plan of care of each patient.

(5) Volunteers. The hospice service program may use volunteers, in defined roles, under the supervision of a designated hospice program employee.

(a) Training. The hospice program must provide appropriate orientation and training that is consistent with acceptable standards of hospice practice.

(b) Role. Volunteers may be used in administrative or direct patient care roles.

1. Recruiting and retaining. The hospice must document active and ongoing efforts to recruit and train volunteers.

2. Availability of clergy. The hospice service program must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request such visits and must advise patients of this opportunity.

(6) Continuation of Care. An organization providing hospice services must assist in coordinating continued care should the patient be transferred or discharged from the hospice program or the organization.

(7) Short Term Inpatient Care. Short term inpatient care is available for pain control, symptom management and respite services, and if not provided directly, must be provided under a legally binding written agreement that meets the requirements of subparagraph (b) of this paragraph in a licensed nursing home, hospital, or residential hospice which meets the following minimum requirements:

(a) Whether provided directly or indirectly, the facility that provides short term inpatient care must provide twenty-four (24) hour nursing services which are sufficient to meet total nursing needs in accordance with the patient's plan of care. Each hospice patient must receive treatments, medications, and diet as prescribed, and must be kept comfortable, clean, well-groomed and protected from accident, injury and infection. Each shift must include a registered nurse (R.N.) who provides direct patient care.

(b) The facility must be designed and equipped for the comfort and privacy of each hospice patient and family member(s) by providing physical space for private patient/family visiting, accommodations for family members to remain with the patient throughout the night, accommodations for family privacy following a patient's death and decor which is home-like in design and function.

(c) The hospice must furnish to the inpatient provider a copy of the patient's plan of care and specify the inpatient services to be furnished.

(d) The inpatient provider must have established policies consistent with those of the hospice and agree to abide by the patient care protocols established by the hospice for its patients.

(e) The medical record must include a record of all inpatient services and events. A copy of the discharge summary must be provided to the hospice and, if requested, a copy of the medical record is to be provided to the hospice.

(f) The written agreement must designate the party responsible for the implementation of the provisions of the agreement.

(g) The hospice shall retain responsibility for appropriate hospice care training of the personnel who provide the care under the agreement.

(8) Drugs and treatments shall be administered by appropriately licensed agency personnel, acting within the scope of their licenses. Oral orders for drugs and treatments shall be given to appropriately licensed personnel acting within the scope of their licenses, immediately recorded, signed and dated, and countersigned and dated by the physician.

(9) Performance Improvement Program. Each agency must conduct an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of past and present care provided, including inpatient care and contract services. The written performance improvement plan findings are to be used by the hospice to determine the appropriateness and effectiveness of the care provided and to ascertain that

professional policies are followed in providing these services. The objectives of those responsible for the performance improvement program are as follows:

(a) To assist the agency in using its personnel and facilities to meet individual and community needs;

(b) To identify and correct problems and/or deficiencies which undermine quality of care and lead to waste of agency and personnel resources;

(c) To help the agency make critical judgments regarding the quality and quantity of its services through self-examination;

(d) To provide opportunities to evaluate the effectiveness of agency policies and when necessary make recommendations to the administration as to controls or changes needed to assure high standards of patient care;

(e) To provide data needed to satisfy state licensure and federal certification requirements; and

(f) To establish criteria to measure the effectiveness and efficiency of the hospice services provided to patients.

(10) Infection Control.

(a) There must be an active performance improvement program for developing guidelines, policies, procedures and techniques for the prevention, control and investigation of infections and communicable diseases.

(b) Formal provisions must be developed to educate and orient all appropriate personnel and/or family members in the practice of aseptic techniques such as handwashing and scrubbing practices, proper hygiene, use of personal protective equipment, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies.

(c) Continuing education shall be provided for all agency patient care providers on the cause, effect, transmission, prevention and elimination of infections, as evidenced by the ability to verbalize/or demonstrate an understanding of basic techniques.

(d) The agency shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the agency, a student studying at the agency or other health care provider rendering services at the agency is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.

(e) The agency and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV and communicable diseases.

(f) Precautions shall be taken to prevent the contamination of sterile and clean supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents.

(11) Home Health Aide/Hospice Aide Services. Home Health Aide Services must be available and adequate in frequency to meet the needs of the patients.

(Rule 1200-8-27-.06, continued)

(a) The home health aide shall be assigned to a particular patient by a registered nurse. Written instructions for patient care shall be prepared by a registered nurse or therapist as appropriate. Duties may include the performance of simple procedures as an extension of therapy services, personal care, ambulation and exercises, household services essential to health care at home, assistance with medications that are ordinarily self-administered, reporting changes in the patient's condition and needs, and completing appropriate records.

(b) The registered nurse, or appropriate professional staff member if other home health services are provided, shall make a supervisory visit to the patient's residence at least monthly, either when the aide is present to observe and assist or when the aide is absent (preferably alternating visits), to assess the aide's competence in providing care and determine whether goals are being met.

(c) There shall be continuing in-service programs on a regularly scheduled basis with on-the-job training during supervisor visits as issues are identified.

(12) Physical Therapy, Occupational Therapy and Speech Language Pathology Services. Physical therapy services, occupational therapy services, and speech language pathology services must be available and when provided, offered in a manner consistent with accepted standards of practice.

(13) Medical Supplies. Medical supplies and appliances, including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness or conditions directly attributable to the terminal diagnosis.

(a) Administration. All drugs and biologicals must be administered in accordance with accepted standards of practice and only by appropriately licensed employees of the hospice.

(b) The hospice must have a policy for the disposal of controlled drugs maintained in the patient's home or temporary place of residence when those drugs are no longer needed by the patient.

(c) Drugs and biologicals may be administered by the patient or his/her family member if the patient's attending physician has approved.

(14) Medical Records.

(a) A medical record containing past and current findings in accordance with accepted professional standards shall be maintained for every patient receiving hospice services. In addition to the plan of care, the record shall contain: appropriate identifying information; name of physician; all medications and treatments; and signed and dated clinical notes. Clinical notes shall be written the day on which service is rendered and incorporated no less often than weekly; copies of summary reports shall be sent to the physician; and a discharge summary shall be dated and signed within 7 days of discharge.

(b) All medical records, either written, electronic, graphic or otherwise acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least ten (10) years after which such records may be destroyed. However, in cases of patients under mental disability or minority, their complete agency records shall be retained for the period of minority or known mental disability, plus one (1) year, or ten (10) years following the discharge of the patient, whichever is longer. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of the contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the agency's policies and procedures, and no record may be destroyed on an individual basis.

(Rule 1200-8-27-.06, continued)

(c) Even if the agency discontinues operations, records shall be maintained as mandated by this Chapter and the Tennessee Medical Records Act (T.C.A. §§ 68-11-308). If a patient is transferred to another health care facility or agency, a copy of the record or an abstract shall accompany the patient when the agency is directly involved in the transfer.

(d) Medical records information shall be safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and conditions for release of information. The patient's written consent shall be required for release of information when the release is not otherwise authorized by law.

(e) For purposes of this rule, the requirements for signature or countersignature by a physician or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established protocol or rules.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-3-511, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-304.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed September 13, 2002; effective November 27, 2002.*

1200-8-27-.07 RESERVED.

1200-8-27-.08 RESERVED.

1200-8-27-.09 RESERVED.

1200-8-27-.10 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each agency must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste. These policies and procedures must comply with the standards of this rule and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(a) Waste human blood and blood products such as serum, plasma, and other blood components;

(b) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass and scalpel blades) used in patient care; and

(c) Other waste determined to be infectious by the agency in its written policy.

(3) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid and puncture-resistant containers which must then be tightly sealed.

(b) Infectious and hazardous waste must be secured in fastened plastic bags before placement in a garbage can with other household waste.

(Rule 1200-8-27-.10, continued)

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.

(4) After packaging, waste must be handled, transported and stored by methods ensuring containment and preserving of the integrity of the packaging, including the use of secondary containment where necessary.

(5) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(6) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the agency must ensure that proper actions are immediately taken to:

(a) Isolate the area;

(b) Repackage all spilled waste and contaminated debris in accordance with the requirements of this rule; and

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000.*

1200-8-27-.11 RECORDS AND REPORTS.

(1) A yearly statistical report, the "Joint Annual Report of Home Care Organizations", shall be submitted to the Department. The forms are mailed to each home care organization by the Department each year. The forms must be completed and returned to the Department as requested.

(2) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

2. aspiration in a non-intubated patient related to conscious/moderate sedation;

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

   (i) procedure related injury requiring repair or removal of an organ;

   (ii) hemorrhage;

   (iii) displacement, migration or breakage of an implant, device, graft or drain;

   (iv) post operative wound infection following clean or clean/contaminated case;

   (v) any unexpected operation or reoperation related to the primary procedure;

   (vi) hysterectomy in a pregnant woman;

   (vii) ruptured uterus;

   (viii) circumcision;

   (ix) incorrect procedure or incorrect treatment that is invasive;

   (x) wrong patient/wrong site surgical procedure;

   (xi) unintentionally retained foreign body;

   (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

   (xiii) criminal acts;

   (xiv) suicide or attempted suicide;

   (xv) elopement from the facility;

   (xvi) infant abduction, or infant discharged to the wrong family;

   (xvii) adult abduction;

   (xviii) rape;

   (xix) patient altercation;

   (xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license

sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.

(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

(3) The agency shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Department licensure surveys;

(b) Federal Health Care Financing Administration surveys and inspections, if any;

(c) Orders of the Commissioner or Board, if any; and

(d) Comptroller of the Treasury's audit report and finding, if any.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-8-27-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days. Suspected abuse of a patient shall be reported immediately to the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq.;

(c) To have appropriate assessment and management of pain;

(d) To be involved in the decision making of all aspects of their care;

(e) To refuse treatment. The patient must be informed of the consequences of that decision. A refusal and its reason must be reported to the physician and documented in the medical record;

(f) To refuse experimental treatment and drugs. The patient's written consent for participation in research must be obtained and retained in his or her medical record; and

(g) To have his or her records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's legal representative. The agency must have policies to govern access and duplication of the patient's record.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment, including resuscitative services. This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed June 18, 2002; effective September 1, 2002.*

1200-8-27-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING FOR INCOMPETENT PATIENTS.

(1) Pursuant to this Rule, each hospice agency shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks decision-making capacity, including but not limited to allowing the withholding of CPR measures from individual patients. The policies and procedures for determining when resuscitative services may be withheld must respect the patient's rights of self-determination. The hospice agency must inform the patient and/or the patient's health care decision-maker of these policies and procedures upon admission or at such time as may be appropriate.

(2) The hospice agency should identify, after consultation with the family or responsible party, the name of the health care decision-maker for a patient who is incompetent or who lacks decision-making capacity, who will be responsible, along with the treating physician, for making health care decisions, including but not limited to deciding on the issuance of a DNR order.

(3) Health care decisions made by a health care decision-maker must be made in accord with the patient's individual health care instructions, if any, and other wishes to the extent known to the health care decision-maker. If the patient's specific wishes are not known, decisions are to be made in accord with the health care decision-maker's determination of the patient's desires or best interests in light of the personal values and beliefs of the patient to the extent they are known.

(Rule 1200-8-27-.13, continued)

(4) In the case of a patient who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's surrogate to make health care decisions on the patient's behalf.

(a) The patient's surrogate shall be an adult who:

1. has exhibited special care and concern for the patient, who is familiar with the patient's personal values, and who is reasonably available; and

2. consideration shall if possible be given in order of descending preference for service as a surrogate to:

(i) the patient's spouse,

(ii) the patient's adult child,

(iii) the patient's parent,

(iv) the patient's adult sibling,

(v) any other adult relative of the patient, or

(vi) any other adult who satisfies the requirement under part 1 above.

(b) If none of the individuals eligible to act as a surrogate under subparagraph (a), is reasonably available, the patient's treating physician may make health care decisions for the patient after the treating physician either (i) consults with and obtains the recommendations of an institutional ethics committee, or (ii) consults with a second physician who (A) is not directly involved in the patient's health care; (B) either (i) does not serve in a capacity of decision-making or influence or responsibility over the treating physician, or (ii) for whom the treating physician does not exert decision-making, influence or responsibility; and (C) concurs with the treating physician's decision. For the purposes of this rule, "institutional ethics committee" means a committee of a licensed health care institution which renders advice concerning ethical issues involving health care.

(5) All patients shall be presumed as having consented to CPR unless there is documentation in the medical record that the patient has specified that a DNR order be written. DNR orders may be written to exclude any portion of the CPR measures deemed to be unacceptable.

(6) In the case of an incompetent patient who has appointed an attorney in fact to act on his or her behalf pursuant to an advance directive or who has a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must reflect that the attorney in fact, guardian or conservator has specified that a DNR order be written. In the case of a patient who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's surrogate to make health care decisions on the patient's behalf, and reflect that the patient's surrogate and the patient's treating physician have mutually specified that a DNR order be written.

(7) CPR may be withheld from the patient if in the judgment of the treating physician an attempt to resuscitate would be medically futile. Withholding and withdrawal of resuscitative services shall be regarded as identical for the purposes of these regulations.

(Rule 1200-8-27-.13, continued)

(8) Procedures for periodic review of DNR orders must be established and maintained. The hospice agency must have procedures for allowing revocation or amending DNR orders by the patient, the patient's health care decision-maker, or treating physician. Such change shall be documented in the medical record.

(9) Any treating physician who refuses to enter a DNR order in accordance with provisions set forth above, or to comply with a DNR order, shall promptly advise the patient or the patient's health care decision-maker of this decision. The treating physician shall then:

(a) Make a good faith attempt to transfer the patient to another physician who will honor the DNR order; and,

(b) Permit the patient to obtain another physician.

(10) Each hospice agency shall establish, and set forth in writing, a mediation process to deal with any dispute regarding health care decisions, including DNR orders, or the determination of the health care decision-maker.

(11) This rule does not alter any requirements imposed by state or federal law, where applicable, including Title 33, the mental health and developmental disabilities law.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-224.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed April 28, 2003; effective July 12, 2003.*

1200-8-27-.14 DISASTER PREPAREDNESS.

(1) All agencies shall establish and maintain communications with the local office of the Tennessee Emergency Management Agency. This includes the provision of the information and procedures that are needed for the local comprehensive emergency plan. The agency shall cooperate, to the extent possible, in area disaster drills and local emergency situations.

(2) A file of documents demonstrating communications and cooperation with the local agency must be maintained.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000.*